

Remarks/Arguments

Claims 50-52, 54-75, 77, 79-95, 97-104 and 108-131 are pending. Claims 1-49, 53, 55, 76, 78, 96 and 105-107 remain canceled. No new matter has been added

103 Rejections

Claims 50-52, 54-75, 77, 79-95, 97-104 and 108-131 remain rejected under 35 U.S.C. §103(a) as being unpatentable over WO 98/07414 in view of Green (5,976,577) or Venkatesh (6,475,510). The Examiner indicated that WO 98/07414 discloses the same process of preparing rapidly dispersing oral dosage forms of hydrophobic compounds as the instant application but does not disclose the additional step of adding at least two rapidly dispersible matrix-forming releasing agents. The Examiner further indicated that both Green and Venkatesh disclose fast dispersing solid dosage forms of various drugs. Applicants traverse this rejection.

The present invention is directed to rapidly disintegrating solid dosage forms for water insoluble compounds which release primary particles stabilized with one or more surface modifiers. (*See*, Specification at page 2, paragraph 0013). The specification discloses that the particles required to practice the claimed invention can be prepared according to methods of certain US patent applications and methods disclosed in WO 98/07414. (*See*, Specification at page 2, paragraph 0010). However, the particles prepared as described in WO 98/07414 are further manipulated in the claimed preparation with the addition of at least two rapidly dispersible matrix-forming agents. (*See*, Specification at page 3, paragraph 18). Neither, adding a rapidly dispersible matrix-forming agent nor a disintegration time of less than 2 minutes is taught or suggested by WO 98/07414.

The teachings of Venkatesh do not cure the deficiencies of WO 98/07414. Venkatesh discloses combinations of dry granules which are compressed into bite-dispersible tablets, whereas the claimed invention recites preparing an aqueous suspension that is dried, milled and then formed into a solid or dried powder. Venkatesh does not teach or suggest the preparation of an aqueous solution but rather teaches blending intra-granular components which form a dry granulation mixture that is combined with other dry ingredients and then compressed into tablets.

(See, Specification at column 4, lines 10-28). Moreover, the Examples in Venkatesh disclose the ingredients and the %w/w, but not the particle size as in the instant specification.

The teachings of Green also do not cure the deficiencies of WO 98/07414. The particle size in Green is much larger than those claimed herein, *i.e.*, generally 75-400 um, more preferably 100-300 um, whereas the instant application claims particle sizes between 0.05-10 um. (See, Green at column 3, lines 15-20 and Specification at Table 1).

Furthermore, the Examples in Green do not address how the drying process affects the particle size. In contrast, the Examples in the instant application disclose how the drying process affects the particle size. Moreover, the Examples show that the combination of active ingredients, bulking agents and other ingredients affect the particle size before and after the drying process. For example, formulations 3-5 do not reconstitute favorably after going through the drying process illustrating that producing a rapidly disintegrating dosage form constitutes more than merely adding bulking agents. (See, Specification at page 5, paragraph 0028 and Table 1). These meaningful attributes are not contemplated by Venkatesh or Green. Accordingly, WO 98/07414 in combination with Green and Venkatesh fail to make obvious Applicants' invention as presently claimed.

Withdrawal of the rejection is thus respectfully requested.

Double Patenting

Claims 50-52, 54-75, 77, 79-95, 97-104 and 108-131 were rejected under obviousness-type double patenting over claims 1-11 of U.S. Patent No. 5,922,355. Claims 50-52, 54-75, 77, 79-95, 97-104 and 108-131 were rejected under the obviousness-type double patenting over claims 1-5 of U.S. Patent No. 6,228,399. Claims 50-52, 54-75, 77, 79-95, 97-104 and 108-131 were rejected under obviousness-type double patenting over claims 1-22 of U.S. Patent No. 6,465,016. Claims 50-52, 54-75, 77, 79-95, 97-104 and 108-131 were provisionally rejected under the obviousness-type double patenting over claims 1, 2, 4-25, 45-47, 52-53, 55-56, 65 and 101-119 of co-pending application U.S. Serial No. 10/260,788. Applicants postpone the filing of a terminal disclaimer until the claims have otherwise reached allowance.

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USSN: 09/443,863

Conclusion

Applicants submit that this paper is fully responsive and that the application is in condition for allowance. Should any questions arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below. With the enclosed three month extension of time, this response is due on or before November 17, 2007. The Commissioner is hereby authorized to charge payment of any fees that may be required, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 28069-546.

Respectfully submitted,

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